



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/280,567 | 03/30/1999 | THOMAS FRANK BUMOL | 0409020136 | 5988 |

25885 7590 12/01/2003

ELI LILLY AND COMPANY
PATENT DIVISION
P.O. BOX 6288
INDIANAPOLIS, IN 46206-6288

| EXAMINER |
|----------|
|----------|

BRANNOCK, MICHAEL T

| ART UNIT | PAPER NUMBER |
|----------|--------------|
|----------|--------------|

1646

37

DATE MAILED: 12/01/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/280,567

Applicant(s)

BUMOL ET AL.

Examiner

Michael Brannock

Art Unit

1646

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 25 July 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 4,5,7-35 and 40-43 is/are pending in the application.
- 4a) Of the above claim(s) 4,5 and 7-35 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) 40-43 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 25 July 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

Art Unit: 1646

DETAILED ACTION

Status of Application: Claims and Amendments

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on July 23, 2003 has been entered.

Applicant is notified that the amendments put forth on 7/23/03, have been entered in full.

Previously pending claims 1-3, 6, 36-39 are canceled. Non elected claims 4, 5, 7-35 have been withdrawn from consideration, as set forth previously. New claims 40-43 have been added.

Response to Amendment

Applicant is notified that any outstanding rejection or objection that is not expressly maintained in this Office action has been withdrawn in view of Applicant's amendments.

Priority

Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 119e as follows:

The later-filed application must be an application for a patent for an invention which is also disclosed in the prior application (the parent or original nonprovisional application or

Art Unit: 1646

provisional application); the disclosure of the invention in the parent application and in the later-filed application must be sufficient to comply with the requirements of the first paragraph of 35 U.S.C. 112. See *Transco Products, Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 32 USPQ2d 1077 (Fed. Cir. 1994).

Applicant's reliance on a priority date of 5/20/98 based on the prior application 60/086074 is not supported by an enabling disclosure of the instantly claimed invention in the 60/086074 application. No specific teachings about the use of FLINT proteins in the treatment of liver disease can be found. At page 36 the specification merely presents to the artisan an invitation to try to find compounds that bind TNFRsol and modify its activities.

A valid claim to priority can, however, be found on page 42 of Application 60/099,643, filed 9/9/98.

New Rejection:

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 40-43 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent Application Publication 2002/0065210, which claims priority to provisional application 60/094,640 filed July 30, 1998, in view of Nagata et al. Science, 267(1449-1456)1995.

Art Unit: 1646

The instantly claimed methods derive from the discovery that FLINT proteins (e.g. SEQ ID NO: 6 and 8) can disrupt the FasL-Fas receptor interaction, see page 6, L26-30 of the instant specification for example. The FasL-Fas receptor interaction is well established in the art as being a key mediator of apoptosis in a variety of cell types, see the Abstract of Nagata et al., and particularly of apoptosis of liver cells in hepatitis, see the second full paragraph of col 3 of page 1454 of Nagata et al. US Patent Application Publication 2002/0065210 discloses that a protein that they term "Decoy Receptor 3" or "DcR3", and is 100% identical to the mature form of SEQ ID NO: 6, that can inhibit FasL-Fas receptor induced apoptosis, see page 5, paragraph 0064. This teaching is also found in the 60/094,640 application at page 23. The 2002/0065210 publication teaches that DcR3 can be employed therapeutically to regulate apoptosis by Fas ligand, e.g. as an antagonist to inhibit Fas induced apoptosis (paragraphs 0124 and 0126, see also page 23 of 60/094,640).

However, the 2002/0065210 publication does not specifically mention the Fas-mediated apoptosis that occurs in the liver during the pathogenesis of the disorders recited in the instantly claimed methods. However, this Fas-mediated involvement in the liver was well established in the art at the time the 60/099,643 application was filed, as exemplified by Nagata et al., discussed above. Thus, it would be obvious to one of ordinary skill in the art, at the time the invention was made, and with reasonable expectation of success, to therapeutically employ a polypeptide having an amino acid sequence 100% identical to SEQ ID NO: 6 so as to inhibit Fas-mediated apoptosis, as taught by the 2002/0065210 publication, and to do so to treat individuals suffering from disorders of the liver, required by the claims, wherein apoptosis was well established to underlie such disorders, and in particular Fas-mediated apoptosis as taught by

Art Unit: 1646

Nagata et al. The motivation to do so is provided by the 2002/0065210 publication wherein it is taught that DcR3 is believed to be a decoy receptor that inhibits Fas-mediated apoptosis (e.g. page 6, L26-30) and by Nagata who teach that Fas mediates apoptosis of hepatocytes during hepatitis (see page 1454, col 3, second full paragraph).

Conclusion

No claims are allowable.

Please note the new official fax number below:

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Brannock, Ph.D., whose telephone number is (703) 306-5876. The examiner can normally be reached on Mondays through Fridays from 10:00 a.m. to 4:00 p.m.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, Ph.D., can be reached at (703) 308-6564.

Official papers filed by fax should be directed to (703) 872-9306. Faxed draft or informal communications with the examiner should be directed to (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

MB

November 26, 2003


YVONNE EYLER, PH.D.
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600